

Applicant's Docket No.

2331/112

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bevilacqua, et al.

Application No.: 09/821,850

Group No.: 1631

Filed: 3/29/01

Examiner: Allen, M.P.

For: System and Methods for Characterizing a Biological Condition or Agent Using Calibrated Gene Expression Profiles

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING DATE OF EITHER A FINAL ACTION  
OR NOTICE OF ALLOWANCE (37 C.F.R. SECTION 1.97(c))

NOTE: An information disclosure statement shall be considered by the Office if filed . . . before the mailing date of either (1) a final action under Section 1.113 or (2) a notice of allowance under Section 1.311, whichever occurs first, provided the statement is accompanied by either a statement as specified in paragraph (e) of Section 1.97 or the fee set forth in Section 1.17(p).

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 4150, Alexandria, VA 22313-1450.

Date: June 13, 2003

FACSIMILE

☐ transmitted by facsimile to the Patent and Trademark Office (703) \_\_\_\_-\_\_\_\_.

Signature

Barbara J. Carter, Ph.D.

(type or print name of person certifying)

(Transmittal of Information Disclosure Statement Before Mailing Date of Final Action or Notice of Allowance--page 1 of 3)

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\$  
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06/18/2003 HNDW61 00000036 09821850 180.00 OP 01 FC:1806

*certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

### **TIME OF TRANSMITTAL OF ACCOMPANYING SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

1. The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either:

- (1) a final action under Section 1.113 or
- (2) a notice of allowance under Section 1.311,

whichever occurs first.

### **STATEMENT OR FEE**

2. Accompanying this transmittal is

*(check either A or B below)*

A. ☐ a statement as specified in 37 C.F.R. Section 1.97(e).

**OR**

B. ☒ the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (**\$180.00**).

### **FEE PAYMENT**

*(complete this item, if applicable)*

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

Fee due \$ \_\_\_\_\_

**METHOD OF PAYMENT OF FEE**

4.

☒ Attached is a check in the amount of \$ 180.00.

☐ Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.

A duplicate of this request is attached.

If any additional fees are due, please charge Account #19-4972.

Reg. No. 651105

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Customer No.: 002101

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\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

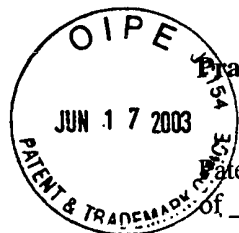
Barbara J. Carter, Ph.D.

*(type or print name of practitioner)*

125 Summer Street, 11<sup>th</sup> Floor

P.O. Address

Boston, MA 02110



Practitioner's Docket No.

2331/112

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Bevilacqua, et al.

Application No.: 09/821,850

Group No.: 1631

Filed: 3/29/01

Examiner: Allen, M.P.

For: System and Methods for Characterizing a Biological Condition or Agent Using Calibrated Gene  
Expression Profiles

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

(Information Disclosure Statement--page 1 of 8)

**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\***  
(When using Express Mail, the Express Mail label number is *mandatory*;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

[x] deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P.O. Box 1450,  
Alexandria, VA 22313-1450.

**37 C.F.R. SECTION 1.8(a)**

[x] with sufficient postage as first class mail.

**37 C.F.R. SECTION 1.10\***

☐ as "Express Mail Post Office to Addressee"

Mailing Label No. \_\_\_\_\_ (mandatory)

**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office.

Date: June 13, 2003

Signature

Barbara J. Carter, Ph.D.

(type or print name of person certifying)

**\*WARNING:**

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).  
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

**NOTE:** "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

**NOTE:** "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

**NOTE:** The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

### List of Sections Forming Part of This Supplemental Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☐ JEPO Search Report
  - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

**NOTE :** "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

## **Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

## Section 2. Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)

*NOTE:* With respect to the list required by paragraph (b) of 37 C.F.R. section 1.98, the Notice of April 20, 1992 (1138 O.G. 37-41) points out that:

*"The list may not be incorporated into the specification but must be submitted in a separate paper. A separate list is required so that it is easy to confirm that applicant intends to submit an information disclosure statement, and because it provides a readily available checklist for the examiner to indicate which identified documents have been considered. A copy of a separate list will also provide a simple means of communication to applicant to indicate the listed documents that have been considered and those listed documents that have not been considered. Use of form PTO-1449, 'Information Disclosure Citation, is encouraged."*

*NOTE:* "An information disclosure statement may include two list[s] ( ) and two certifications[ ]... in situations where some of the information listed was cited in a communication from a foreign patent office not more than three months prior to filing the statement and some was not, but was not known more than three months prior to filing the statement." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

*NOTE:* With respect to the examiner's consideration of the Information Disclosure Statement, the Notice of April 20, 1992 (1138 O.G. 37-41) states:

*"If information is listed in the specification rather than in a separate paper, or if the other content requirements \*\*\* are not complied with, the examiner will notify applicant in the next Office action that the information has not been considered. It should be noted, however, that no copy of a U.S. patent application is required to be submitted. \*\*\* Where a U.S. patent application is properly cited, the examiner should obtain access to that file within the Office."*

*"Examiners must consider all citations submitted in conformance with the rules and this section and place their initials adjacent [sic] the citations on a list or in the boxes provided on a form PTO-1449. If the citations are submitted on a list other than a form PTO-1449, the examiner may write "all considered" and his or her initials to indicate that all citations have been considered. If any of the citations are considered, a copy of the submitted list or form, as reviewed by the examiner, will be returned to the applicant with the next communication. The original copy of the form will be entered into the application file. The copy returned to applicant will serve both as acknowledgement of receipt of the information disclosure statement and as an indication that the references were considered by the examiner. Forms PTO-326 and PTOL-37 include a box to indicate the attachment of form PTO-1449."*

*"Information which complies with requirements as discussed in this section but which is in a non-English language will be considered in view of the concise explanation submitted \*\*\* and insofar as it is understood on its face, e.g., drawings, chemical formulas, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches. The examiner need not have the information translated unless it appears to be necessary to do so. \*\*\* The examiner should not require that a translation be filed by applicant. The examiner should not make any comment such as that the non-English language information has only been considered to the extent understood, since this fact is inherent"*

*"Since information is required to be listed in a separate paper rather than in the specification, there is no need to mark "All checked" or "Checked" in the margin of a specification containing citations."*

*"If a statement fails to comply with the requirements as discussed in this section for an item of information, a line should be drawn through the citation to show that it has not been considered. The other items of information listed that do comply with the rules and this section will be considered by the examiner and will be appropriately initialed."*

\* \* \* \* \*

*"A citation listed on form PTO-1449 and considered by the examiner in accordance with this section will be printed on the patent. A citation listed in a separate paper, equivalent to but not on form PTO-1449, and considered by the examiner in accordance with this section will be printed on the patent if the list is on a separate sheet which is clearly identified as an information disclosure statement and the list lends itself to easy capture of the necessary information by the Office printing contractor, i.e., each item of information is listed on a single line, the lines are at least double-spaced from each other, the information is uniform in format for each listed item, the list includes a column for the examiner's initials to indicate that the information was considered. If a citation is not printed on the patent but has been considered by the examiner in accordance with this section, the patented file will reflect that fact..."*



SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Bevilacqua, et al. Attorney Docket: 2331/112  
 Serial No: 09/821,850 Art Group Unit: 1631  
 Date Filed: 3/29/01 Examiner Name: Allen, M.P.  
 Invention: System and Methods for Characterizing a Biological Condition or Agent Using  
 Calibrated Gene Expression Profiles

LIST OF PATENTS AND PUBLICATIONS FOR  
 APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	DB	Wittwer, Carl T., et al.	"Rapid Thermal Cycling and PCR Kinetics," Academic Press, PCR Applications, 1999, pgs 211-231
	DC	Beasley, Ellen M., et al.	"Statistical Refinement of Primer Design Parameters," Academic Press, PCR Applications, 1999, pgs, 59-71
	DD	Pfeffer, U.	"One-Tube RT-PCR With Sequence-Specific Primers," <i>Methods of Molecular Biology</i> , Vol. 86, pgs. 149-151
	DE	Wiedbrauk, Danny L, et al.	"Nucleic Acid Detection Methods," <i>Molecular Methods for Virus Detection</i> , Academic Press, 1995, pgs. 1-26
	DF		PE Applied Biosystems Manual, "The TaqMan <sup>TM</sup> PCR Reagent Kit Protocol", May 1996

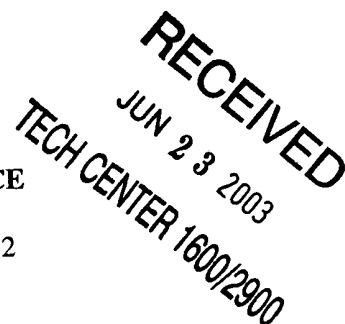
Examiner Signature:

\_\_\_\_\_

Date Considered:

\_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.



## Section 6. Copies of Listed Information Items Accompanying This Statement

*NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."*

*NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

☐ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

**Section 10. Identification of Person(s) Making This Supplement Information Disclosure Statement**

The person making this certification is

*(check each applicable item)*

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Reg. No.: 651105

Tel. No.: (617) 443-9292

Customer No.: 002101

02331/00112 255804.1

  
\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**

Barbara J. Carter, Ph.D

\_\_\_\_\_  
*(type or print name of practitioner)*

125 Summer Street, 11<sup>th</sup> Floor

\_\_\_\_\_  
P.O. Address

Boston, MA 02110